

REMARKS

By this Amendment, the specification is amended, claims 25-40 are cancelled, claims 2-13, 15, 16, and 21 are amended, and new claim 41 is added. Claim 41 is directed to the subject matter of elected Group I.

The specification is amended solely to correct an obvious typographical error in paragraph 31. Support for the amendments to claims 2-13, 15, 16, and 21 comes from the specification and claims, as originally filed, for example at paragraph 29. Accordingly, no new matter is added by this Amendment. Currently, claims 1-24 and 41 are pending, claims 8-16 having been withdrawn by the Examiner as directed to a non-elected invention.

I. *Restriction Requirements*

The Office makes the Restriction Requirements FINAL. (Office Action at paragraph 1.) While not agreeing with the Office on the propriety of the Restriction Requirement, to expedite allowance of this application, by this Amendment, Applicants have cancelled the claims of Groups III, IV, V, VI, and VII. Applicants explicitly reserve the right to prosecute the claims of these Groups in one or more divisional applications.

The claims of Group II (claims 8-16) have been maintained in the application in view of the re-joinder policy of the PTO (see MPEP § 821.04). Applicants request that, upon concluding that the claims of Group I are allowable, the claims of Group II be re-joined and examined in this application.

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Applicants note that claim 12 is directed to the probe or primer of claim 7, and thus should be included with Group I.

With regard to restriction of the claims based on Sequence Identifier numbers, Applicants respectfully request that the Office reconsider its dismissal of Applicants' previous arguments, and examine all of the Sequence Identifiers recited in the present claims in this application because they are all related.

Applicants note that current PTO policy is to examine up to 10 sequences in a single application, regardless of whether the sequences are related or not. MPEP § 803.04. Accordingly, even if, upon reconsideration, the Office does not find the sequences of SEQ ID NOS:1-30 to be related, Applicants request that the Office withdraw the Restriction Requirement at least with respect to 10 of the Sequence Identifiers recited in the present claims (*i.e.*, examine nine sequences in addition to elected SEQ ID NO:1). For example, the Office could examine SEQ ID NO:1-10 in the present application.

## II. *Claim Objection*

The Office objects to claims 1-7 and 17-20 for reciting non-elected Sequence Identifiers. (Office Action at paragraph 2a.) Applicants request that the Office hold this objection in abeyance until it has reconsidered the Restriction Requirement (as it relates to Sequence Identifiers) in view of MPEP § 803.04.

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III. *Rejection Under 35 U.S.C. §§ 101 and 112, first paragraph*

The Office rejects claims 1-7, 17-24, 30, 31, and 40 under 35 U.S.C. §§ 101 and 112, first paragraph, as lacking a well known utility or a specific, credible, and substantial asserted utility. (Office Action at paragraphs 3a and 3b.) The Office bases these rejections on the asserted lack of data in the specification showing that the ABCC11 protein is involved in a disease state. By this Amendment, claims 30, 31, and 40 are cancelled, rendering the rejections moot as they apply to those claims. Applicants respectfully traverse these rejections as they apply to claims 1-7 and 17-24 (and as they might be applied to claims 8-16 and 41), and submit that the present specification discloses a specific, credible, and substantial utility for the nucleic acids, vectors, cells, methods, and kits of the currently pending claims. In addition, Applicants submit that this utility is fully enabled by the specification.

The Office bases its rejections on an asserted lack of utility for the protein encoded by the nucleic acids of the present claims. However, the Office fails to appreciate that the present specification discloses that the nucleic acids of the present invention are useful not only for expressing the ABCC11 protein, but also for identifying the 16q12 locus on human chromosome 16, and investigating changes at this locus. See the specification at paragraphs 13, 106, 210, 242, 278, Example 2 (paragraphs 439-441), and Figure 2, for example. Regardless of whether the Office believes enough information is presented in the specification to show that the ABCC11 protein is involved in a disease state, the fact that the nucleic acids of the claims (including those having at least 80% nucleotide identity with SEQ ID NO:1) can be used to identify a specific locus on human chromosome 16 (*i.e.*, used as probes for a chromosomal marker) provides a

specific, credible, and substantial utility for the nucleic acids of the present claims that would be immediately recognized by those of skill in the art. Thus, for example, it would be immediately apparent to one of skill in the art upon reading the present specification that the presently claimed nucleic acids could be used to determine or confirm the location of other genes on human chromosome 16, particularly those in the 16q12 region.

With regard to the vectors and cells of the claims, one of skill in the art would understand that they are useful for producing nucleic acids that are specific for the ABCC11 gene, and thus are useful for producing the ABCC11-specific probes of the present invention. Applicants submit that this is a specific, credible, and substantial utility.

Likewise, the methods and kits of non-elected claims 8-11 and 13-16 are useful for detecting the 16q12 locus of human chromosome 16, for example. Thus, they are useful for detecting the 16q12 locus of human chromosome 16. Applicants submit that this is a specific, credible, and substantial utility.

Because all of the currently pending claims have a well known utility or a specific, credible, and substantial utility, the present claims satisfy the utility requirement of 35 U.S.C. § 101. Accordingly, one of skill in the art would know how to use the nucleic acids, probes, primers, vectors, cells, and kits of the claims, and how to perform the methods of the claims. For at least this reason, Applicants submit that the claims satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph.

In view of the above comments, Applicants respectfully request that the Office reconsider and withdraw the outstanding rejections under 35 U.S.C. §§ 101 and 112, first paragraph.

IV. *Rejections Under 35 U.S.C. § 112, second paragraph*

The Office rejects claims 5-7 under 35 U.S.C. § 112, second paragraph, as indefinite for reciting "high stringency conditions", and "ABCC11" without first disclosing the entire name of the gene. (Office Action at paragraphs 4a and 4b.) While not necessarily agreeing with the Office on these points, to expedite allowance of this application, claim 5 has been amended to recite hybridization "in the presence of 50% formamide and 6X SCC", and claim 6 has been amended to recite the full name of the ABCC11 gene. In view of these changes to the claims, Applicants request that the Office reconsider and withdraw the rejections under 35 U.S.C. § 112, second paragraph.

V. *Rejection Under 35 U.S.C. § 102*

The Office rejects claims 5 and 6 under 35 U.S.C. § 102(b) as anticipated by Strausberg *et al.* (Office Action at paragraph 5a.) By this Amendment, claims 5 and 6 are amended to eliminate SEQ ID NO:1 and SEQ ID NO:30, which include the sequence identified by the Office as having identity with Strausberg *et al.* The amendments to the claims address the rejection of the Office; thus, the reasoning underlying the rejection is rendered moot. Accordingly, Applicants respectfully request that the Office reconsider and withdraw the rejection of claims 5 and 6 as anticipated by Strausberg *et al.*

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VI. *Conclusion*

Applicants submit that this application is in condition for allowance. Therefore, Applicants request that the Office reconsider and withdraw the outstanding objections and rejections, extend the examination to at least 10 Sequence Identifiers, re-join withdrawn claims 8-16, and issue a Notice of Allowance. If the Office believes anything further is necessary in order to place this application in even better condition for allowance, Applicants request that their undersigned representative be contacted at the telephone number or e-mail address listed below.

Please grant any extension of time required to enter this Amendment, and charge any required fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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